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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,326	07/10/2003	Bastiaan Driehuys	PM0026 DIV	2824

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,326	DRIEHUYS ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/10/03; 11/19/03; and 8/14/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-69 and 80* is/are pending in the application.

4a) Of the above claim(s) *80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/19/03 & 7/10/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/10/03 wherein the specification was amended and claims 1-63, 70-79, and 81-88 were canceled. In addition, the Examiner acknowledges the amendment filed 11/19/03 wherein the specification was amended.

Note: Claims 64-69 and 80 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a method of evaluating the efficacy of targeted drug therapy and a method of preparing a gas container as set forth in independent claims 64 and 80.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election without traverse of Group VII in the reply filed on 8/14/06 is acknowledged. Thus, the restriction is deemed proper and is made FINAL.

Note: Group VII is drawn to a method of evaluating the efficacy of a targeted drug therapy wherein the treatment condition is cardiac/pulmonary and a pharmaceutical preparation is administered.

WITHDRAWN CLAIM

4. Claim 80 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTIONS

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 64-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26 and 30 of copending Application No. 10/356,240. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a pharmaceutical agent, generating an image, and evaluating image data. While the steps are not the same, a skilled practitioner in the art would recognized (1) that in both cases, the effect of a pharmaceutical administered to a subject is being evaluated and (2) the steps of the instant invention are encompassed by those of 10/356,240 which contain more details as to how the NMR data is obtained and analyzed. It should be noted that the step of claim 66 (instant invention) is inherent since if one is evaluating the imaging data from the target area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 64-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49 and 53 of copending Application No. 10/761,794 Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a pharmaceutical agent, generating an image, and evaluating image data. While the steps are not the same, a skilled practitioner in the art would recognized (1) that in both cases, the effect of a pharmaceutical administered to a subject is being evaluated and (2) the steps of the instant invention are encompassed

by those of 10/761,794 which contain more details as to how the NMR data is obtained and analyzed. It should be noted that the step of claim 66 (instant invention) is inherent since if one is evaluating the imaging data from the target area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 64-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 12, 13, 15, 17, 19, 20, and 31 of U.S. Patent No. 6,630,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a pharmaceutical agent, generating an image, and evaluating image data. While the steps are not the same, a skilled practitioner in the art would recognized (1) that in both cases, the effect of a pharmaceutical administered to a subject is being evaluated and (2) the steps of the instant invention are encompassed by the patented invention which contain more details as to how the NMR data is obtained and analyzed. It should be noted that the step of claim 66 (instant invention) is inherent since if one is evaluating the imaging data from the target area.

9. Claims 64-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 24-34 of U.S. Patent No. 6,808,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a

pharmaceutical agent, generating an image, and evaluating image data. While the steps are not the same, a skilled practitioner in the art would recognized (1) that in both cases, the effect of a pharmaceutical administered to a subject is being evaluated and (2) the steps of the instant invention are encompassed by those of the patented invention which contain more details as to how the NMR data is obtained and analyzed. It should be noted that the step of claim 66 (instant invention) is inherent since if one is evaluating the imaging data from the target area.

103 REJECTIONS

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larsen et al (US Patent No. 6,453,188).

Ardenkjaer-Larsen et al disclose a method of magnetic resonance imaging wherein a hyperpolarizable gas is administered to a subject along with a imaging agent and optionally, generating an image or biological functional data or dynamic flow data from the detected signal (see entire document, especially, abstract; column 2, lines 28-50; column 3, lines 9-18; column 8, lines 18-27). A suitable gas that may be hyperpolarized is 129Xe (column 2, lines 51-67). The imaging agent may be formulated

with conventional pharmaceutical or veterinary carriers or excipients. The formulations may include stabilizers, antioxidants, osmolality adjusting agents, solubilizing agents, emulsifiers, viscosity enhancers, and buffers. The formulations may be administered directly into body cavities such as the lungs or injected or infused into the cardiovascular system (column 10, lines 17-38). The imaging agent may be injected simultaneously at a series of administration sites such that a greater proportion of the vascular tree may be visualized before the polarization is lost through relaxation (column 11, lines 20-26). Once the imaging agent has been administered to the subject, the procedure for detecting the magnetic resonance signals is that which is well known in the art (i.e., echo planar imaging, spiral scan, etc.) [column 11, lines 33-39]. The technique of Ardenkjaer-Larsen et al may be used as a diagnostic tool such that images may be obtained 4-5 second post injection (column 11, lines 40-48). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to evaluate the efficacy of a targeted drug therapy as set forth in independent claim 64 because Ardenkjaer-Larsen et al disclose a method of magnetic resonance imaging wherein a pharmaceutical composition is administered to a subject in combination with a hyperpolarizable gas such as 129Xe and an image is generated and data is analyzed. Furthermore, it would be obvious to use the procedure disclosed in Ardenkjaer-Larsen et al for treatments involving a cardiac/pulmonary condition because the reference discloses in column 10, lines 30-36, that the pharmaceuticals formulations may be used for applications such as external voidance ducts such as the lungs or the formulation may be injected or infused into the cardiovascular system.

COMMENTS/NOTES

12. Applicant is respectfully requested to amend the claims to read on the elected invention.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

October 30, 2006